

## Media Release



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Basel, 1 April 2005

### **Xeloda wins EU approval for adjuvant therapy in the treatment of colon cancer**

**Colon cancer patients have access to a new, more convenient and safer treatment option compared to the current standard of therapy**

Roche announced today that the European authorities have approved Xeloda (capecitabine), an innovative oral chemotherapy, to be used as an adjuvant treatment (post-surgery) for colon cancer. Patients will now have the choice of an effective, convenient chemotherapy that prolongs cancer free life, with a less serious side effect profile compared to the current standard treatment of intravenous 5-fluorouracil/leucovorin (i.v. 5-FU/LV).

Adjuvant chemotherapy is the standard treatment approach for stage III colon cancer where chemotherapy is given in order to destroy any cancerous cells remaining in the body after the tumour has been surgically removed.

"The European approval for Xeloda's new indication, again confirms Roche's commitment to providing innovative solutions for patients, whilst providing medical resource cost savings for today's healthcare providers" said William M. Burns, CEO of Roche's Pharmaceutical Division.

"For the first time colon cancer patients will have access to a unique treatment option that provides an effective oral therapy which is well-tolerated and can be taken at home."

"As the European approval decision was based on the landmark X-ACT trial, which showed that Xeloda should replace standard intravenous chemotherapy 5FU/LV, physicians and patients can be fully confident that they are using a very effective, safe and convenient treatment that is now available." said Professor Jim Cassidy, Cancer Research UK Professor of Oncology and Chair of Medical Oncology, Beatson Oncology Centre, at the University of Glasgow in Scotland.

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The landmark X-ACT (Xeloda in Adjuvant Colon Cancer Therapy) trial which successfully met its primary endpoint, demonstrated that Xeloda is at least as effective compared to intravenous 5-FU/LV in terms of disease-free survival with a superior reduction in the risk of cancer recurrence (relapse-free survival).<sup>1</sup>

In addition, on average, a patient only needed 8 hospital visits when treated with Xeloda compared to 30 visits if treated with i.v. 5-FU/LV.<sup>2</sup> This results in significant cost savings, an important advantage for doctors, nurses and pharmacists in today's healthcare environment.

In 2004 approximately 88,000 patients in Europe who had advanced colorectal or breast cancer benefited from Xeloda. Based on the new indication approximately 55,000 colon cancer patients a year can now also be treated with this effective and convenient oral cancer treatment. Global sales in 2004 were 534 million Swiss francs and are expected to accelerate in 2005.

#### About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life.

Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai.

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#### Further Information:

- Presentation of the X-ACT trial: <http://www.asco.org/ac/1.1003.12-002511-00.12-0026-00.19-009534-00.21-004100.asp>, "Capecitabine vs. bolus 5-FU/leucovorin as adjuvant therapy for colon cancer (the X-ACT study): positive efficacy results of a phase III trial"
- Colorectal cancer: <http://www.roche.com/pages/downloads/company/pdf/mbg010495c.pdf>
- Xeloda in colorectal cancer: <http://www.roche.com/pages/downloads/company/pdf/mbg0104105xc.pdf>
- Xeloda: <http://www.roche.com/pages/downloads/company/pdf/mbg0104105x.pdf>

- Roche in oncology:  
[http://www.roche.com/pages/downloads/company/pdf/mboncology05e\\_a.pdf](http://www.roche.com/pages/downloads/company/pdf/mboncology05e_a.pdf)
- Roche: [www.roche.com](http://www.roche.com)
- Broadcast quality B-roll including doctor and patient interviews is available for download via [www.thenewsmarket.com](http://www.thenewsmarket.com)

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#### References:

1. Reddy, G. Efficacy of adjuvant capecitabine compared with bolus 5-Fluorouracil/Leucovorin regimen in Dukes C colon cancer: results from the X-ACT trial. *Clin Colorectal Cancer*, July 2004: 67-68.
2. McKendrick, J.J., Cassidy, J., et al. Capecitabine (x) is resource saving compared with i.v. bolus 5-FU/LV in adjuvant chemotherapy for Dukes' C colon cancer patients: Medical resource utilization (MRU) data from large phase III trial (X-ACT). *Journ of Clin Oncol*, 2004 ASCO Annual Meeting Proceedings (Post Meeting Edition). Vol 22, No 14S (July supplement), 2004: 3578